UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,320	02/13/2001	Bernhard H. van Lengerich	BVL-102A	9819

7590 07/31/2012

Douglas J. Taylor, Esq.
General Mills, Inc.
P.O. Box 1113
Minneapolis, MN 55440

EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
07/31/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/782,320	VAN LENGERICH, BERNHARD H.	
	Examiner	Art Unit	
	LEZAH ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2012*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

5a) Of the above claim(s) *94* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *25-31, 34, 35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105 and 108-112* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *28 Mar 2012*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 25-31, 34, 35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 81-85, 91--97, 101, 103, 105 and 108-112 .

DETAILED ACTION

Applicants' arguments, filed March 28, 2012, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

It is noted that the Obvious Double Patenting Rejection made on March 17, 2003 was erroneously withdrawn before the Terminal Disclaimer filed on June 18, 2003 was approved. The Terminal Disclaimer was disapproved on April 12, 2012 and therefore the Obvious Double Patenting Rejection has been reinstated. Therefore this Office Action is Non-Final.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejections)

1) Claims 25, 26, 28, 30, 31, 35, 37-40, 46, 91, 92, 101, 108 and 109 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Schiltz (US 5,449,708) in view of Farquharson et al. (US 4,888,174).

Rejection

Schiltz discloses starch-based biodegradable polymers. It is a homogeneous mixture of starch, an ethylene acrylic acid co-polymer, and a salt of stearic acid (a fatty acid of instant claim 31, also has a hydrophobic component meeting instant claim 30). An aqueous lubricant material is then added to the mixture. Excess moisture is removed under reduced pressure and a plastic material is extruded (Abstract), meeting the limitation of plasticized matrix. The starch is 20% to 90% by weight of the total composition (col. 4, lines 52-56), meeting instant claims 25 and 39. The starch component is substantially gelatinized before and during its mixture with the copolymer and/or additional polymeric components, meeting the limitation of instant claim 26. The compositions may be formulated into pellets, powders, granules and regrind (col. 11, lines 66-68), meeting instant claim 28. The components are mixed to achieve a homogeneous mixture (col. 4, lines 17-20). Other additives include anti-oxidants (meeting instant claim 46), stabilizers, herbicides, fungicides and fertilizers. The additives may be added in amounts necessary to achieve the desired effect in a manner entirely consistent with the continuous method described herein (col. 7, lines 56-59). The starch may be obtained from corn, wheat, rice, potato and tapioca (col. 7, lines 65-68). Gelatinization disrupts the starch granules providing access to individual starch molecules (col. 8, lines 14-20). The residual moisture during processing the compositions plasticize the starch (col. 6, lines 56-63), meeting the limitation that the plasticizer comprises water. Polyethylene is further provided as an additional polymeric material (col. 4, lines 21-25).

The reference differs from the instant claims insofar as it does not disclose the amount of additive incorporated into the compositions or the size of the films or pellets.

Farquharson et al. disclose a composition comprising an insecticide and a polymer. The compositions may be formulated into films. The compositions may be incorporated into polymer pellets. The size of the pellet can range in diameter from about 1/16 to about 1/2 inch (1.58 mm to 12.7 mm), meeting instant claims 35, 37 and 40. The film thickness ranges from 0.5 mil to about 4 mil (0.0127 to 6.35 mm) (col. 6, lines 35-50).

The reference differs from the instant claims insofar as it does not disclose the films comprise starch.

It would have been obvious to one of ordinary skill in the art to have made the pellets of Schiltz a size where the diameter ranges from 1/16 to ½ inch motivated by the desire to make pellets a size disclosed by the art as suitable for pellets used in agriculture.

Schiltz discloses temperature ranges up to 135 degrees C (col. 4, lines 4-20) similar to those disclosed by the instant specification up to 160 degrees C and below the decomposition temperature of starch. Thus it is reasonable to conclude that the starches used by Schiltz are not “substantially dextrinized” or “substantially destuctured”.

In regard to the amount of encapsulant, Schiltz discloses the additives may be added in amounts necessary to achieve the desired effect in a manner entirely consistent with the continuous method described herein. Therefore it would have taken

no more than the relative skill of one of ordinary skill in the art to have adjusted the amount of additive to obtain the desired effect. It would have been obvious to one of ordinary skill in the art to have used the additives in amount ranging from 1% to 85% motivated by the desire to obtain the desired effect of the additive.

The prior art does not disclose the exact claimed values of about 40% or more and 60% to 95% of at least on matrix material and up to about 10 mm, but does overlap disclosing 20% to 90% starch and a diameter ranging from 1.58 to 12.7 mm: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore it would have been obvious to one of ordinary skill in the art to have used starch in an amount of 40% or more and made a pellet with a diameter of up to about 10 mm consistent with the In re Peterson decision.

Response to Arguments

Applicant's Arguments

Applicant argues that the claimed products would not be obtained or rendered obvious. Schiltz clearly wants to destroy the starch granules so that the individual starch molecules or amylose can interact with the copolymer and polyethylene to form a polymer composite because it discloses gelatinization disrupts the starch granules. The temperature is not the only parameter affecting dextrinization and destructurization of starch. The parameter affecting dextrinization and destructurization include low shear mixing, low temperature and plasticizer amounts, and extrusion residence time, screw

speeds, and screw configuration are employed to achieve plasticization without substantial destructurization or dextrinization of the starch. Schiltz does not teach or suggest avoiding destructuring or dextrinization, or the use of the above parameters to achieve plasticization without substantial destructurization or dextrinization of the starch. To the contrary, Schiltz employs a critical pH of 10-12, preferably accomplished with the addition of sodium hydroxide, to disrupt the starch granules and provide access to individual starch molecules to achieve interaction between the components to obtain a polymer composite. Farquharson et al does not cure the above-discussed deficiencies in the disclosure of Schiltz. Farquharson et al do not disclose the use of starch or avoiding destructurization or dextrinization of starch. Even if the pellet sizes employed by Farquharson et al were used in the process of Schiltz, applicant's claimed invention would not be obtained or rendered obvious.

Examiner's Response

The Examiner submits that the instant claims recite using pre-gelatinized starch in the compositions and therefore one of ordinary skill in the art would conclude that what Applicant considers “destructured” and “dextrinized” would not include gelatinized starches. Further, the claims recite "not substantially destructured or dextrinized", which indicates that the starch may be one or the other (either “not substantially destructured” or "not substantially dextrinized”) or both. Therefore even if the starch is substantially destructured as applicant argues, the granules are “not substantially dextrinized", meeting the limitation of "not substantially destructured or dextrinized". Further, the

instant claims or the instant specification do not define what is encompassed by the terms "substantially destructured" or "substantially dextrinized" and therefore the claims are interpreted broadly. Further the instant specification discloses that the plasticized composition forms a melt, which indicates that the starch granules of the instant claims undergo some type of disruption. Therefore based on the above, it does not appear that the starches of Schiltz are "not substantially destructured or dextrinized" because the starches of the instant claims may be pre-gelatinized and form melts. In regard to Farquharson, the reference discloses the size of pellets used for insecticides. Therefore one of ordinary skill in the art would be motivated to make the pellets of Schiltz the sizes disclosed by Farquharson et al. because they are a suitable size for pellets used in agriculture.

2) Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 69, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 were rejected under 35 U.S.C. 103(a) as being unpatentable over Loomis et al. (US 5,852,114) in view of Newton et al. (US 4,938,967). The rejection is maintained and further applied to new claims 111 and 112.

Rejection

Loomis et al. disclose biodegradable thermoplastic polymer blends comprising a first polymer and a second polymer. The polymers form a homogeneous blend (Abstract). The first polymer includes hydrophobic polymers and may comprise 20% to

80% by weight of the total composition. Polymers also include polyvinyl pyrrolidone meeting instant claims 50 and 79. The second polymer ranges from about 10% to 70% by weight of the total composition and includes polyvinyl acetate copolymers, pectins, polysaccharides, starch, cellulose and alginates. A starch component is also incorporated into the composition to impart further desirable physical properties and characteristics (col. 4, lines 63-67). The starch component includes native or granular starch, chemically modified starch, gelatinized starch and destructurized starch and combinations thereof, meeting the limitations of instant claim 54, 108 and 109. Native and granular starch is selected from potatoes, rice, tapioca, corn, rye, oats, wheat and combination thereof. The starch component may comprise 5% to about 50% (col. 8, lines 36-52). Optional components, which may also be added to the compositions of the present invention to impart further desirable physical properties and characteristics, may be selected from the group consisting of extenders; fillers; lubricants; mold-release agents; ultraviolet stabilizers; coloring agents; anti-oxidants (instant claims 46 and 75) and combinations thereof. Lubricants include stearates and lecithin (instant 30 and 31). Stabilizers include antimicrobial agents. Extenders include soybean proteins and gelatin (col. 9, line 54 to col. 10, line 46), meeting the limitation of instant claims 52, 54, 83, 108 and 109. The compositions may be used for the controlled delivery of pharmaceuticals or agricultural chemicals (col. 13, lines 1-5). The compositions are formulated into granule, pellets or powders (col. 11, lines 27-35), meeting instant claims 28 and 55. The reference discloses water is removed and therefore water is present meeting the limitation of the plasticizer comprising water.

The reference differs from the instant claims insofar as it does not disclose the dimensions of the granules, pellets or powders; or the amount of optional components that may be added to the compositions.

Newton et al. disclose pharmaceutical compositions. The dosages are preferably capsules that contain one or more units. Density of conventional tablets and pellets is usually about 1.0 to 1.5 g/ml (1000 to 1500 g/liter) (col. 1, lines 11-13), encompassing claim 34. Selection of the binder determines the rate of release of the active ingredient (col. 1, lines 19-21). The dosage may be a plurality of pellets having a dimension below about 2 mm, encompassing claims 25, 28, 35, 37 and 55. The pellets have a shape that is spherical (col. 7, lines 48-57) (instant claims 35, 37 and 40). The active ingredient comprises 0.0001 to 45% of the compositions (col. 10, lines 30-35). Various active agents may be used such as tonics (encompassing claim 93), anti-inflammatory, enzymes (instant claim 82) and anti-viral agents (col. 13 to col. 14, line 48). The pellets may comprise a matrix binder and a coating. These serve to control the release of the active. Binders include polymers such as starch and cellulose (col. 8, lines 53-68). Generally water is added to the compositions to aid in pelletisation (col. 11, lines 37-39), encompassing a water plasticizer. The matrix binder may comprise 50% of the particles (col. 10, lines 22-25). Each pellet may comprise a homogeneous blend of the active, the weighing material and the matrix binder components (col. 10, lines 58-60). Magnesium stearate also may be added to the compositions (Example 3), encompassing claims 31 and 59.

Newton et al. differ from the instant claims insofar as it does not disclose the exact amounts of matrix material or encapsulant as recited in the instant claims and does not disclose a plasticized matrix comprising starch.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have formulated the pharmaceutical compositions of Loomis with the dimensions and the amounts disclosed by Newton motivated by the desire to use formulations known in the art for making pharmaceutical compositions.

It would have been obvious to have coated the actives before incorporating them into the matrix of Loomis et al. motivated by the desire to add an additional control release mechanism for the active agent as suggested by the teachings of Newton et al.

Newton et al. disclose the active may comprise 0.0001 to 45% of the compositions. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore it would have been obvious to have used 1 to 85%, 5% to 50%, 3% to 50% and 5% to 20% of encapsulant (active agent) in the compositions of Loomis in view of Newton et al. consistent with the In re Peterson decision.

Loomis et al. disclose temperature ranges from 120 to 180 degrees C (col. 3, lines 3-8) similar to those disclosed by the instant specification up to 160 degrees C.

Thus it is reasonable to conclude that the starches used by Loomis et al. are not "substantially dextrinized".

In regard to claims 38 and 64, the rate of release is controlled by the matrix material. The matrix materials of the instant claims comprise substantially the same components, a plasticized matrix comprising starch and a rate controlling agent as the compositions of the combined reference. Therefore one of ordinary skill in the art would reasonably conclude that the compositions would release the encapsulant in an aqueous or gastric juice environment in an amount of no more than from about 10% in about 1 hour to no less than about 90% in about 24 hours as recited by the instant claims.

Response to Arguments

Applicant's Arguments

Applicant argues that neither Loomis et al nor Newton et al, taken alone or in combination teach or suggest the use of a plasticized mass comprising starch which is not substantially destructured or dextrinized. Even if the references were properly combinable, applicant's claimed products would not be obtained or rendered obvious. Applicant asserts that pectins, polysaccharides, starch, cellulose and alginates, and a starch component disclosed by Loomis are not disclosed as a second polymer, but rather may be added to the first and second polymers. Loomis discloses the use of extrusion temperatures of 170 to 205°C in the blending zone and within the range of 210 to 225°C in the last zone and the extruder die, not 120 to 180°C as asserted by the

Examiner. Moreover, applicant's claims recite that the starch is not substantially destructured. Loomis desires destructured starch and employs extrusion conditions to destructure starch. Based on the conditions used to make the composition disclosed by Loomis et al., Loomis et al does not teach or suggest avoiding destructuring or dextrinization, or the use of low shear or high amounts of plasticizer, or extrusion residence time, screw speeds, and screw configurations to achieve plasticization without substantial destructurization or dextrinization of the starch. To the contrary, Loomis et al employs high extrusion temperatures, a high L/D, intensive mixing conditions, and low moisture contents to obtain destructured starch and a thermoplastic composition. Further, Newton et al does not cure the above-discussed deficiencies in the disclosure of Loomis et al. Even if the references were properly combinable, employment of a starch binder of Newton et al in the process and composition of Loomis et al would still result in substantial destructurization of the starch because it would be subjected to the intense extrusion conditions of Loomis et al.

Examiner's Response

The Examiner submits that the instant claims recite the transitional language of "comprising" and therefore the reference is only required to comprise starch. Therefore the disclosure that Loomis adds starch to a first and second polymer would meet the limitations of the instant claims. In regard to the starches of Loomis et al. being destructured, it is submitted that the instant claims recite using partially gelatinized starch in the compositions and therefore one of ordinary skill in the art would conclude

that what Applicant considers “destructured” and “dextrinized” would not include gelatinized starches. Further, the claims recite "not substantially destructured or dextrinized", which indicates that the starch may be one or the other (either “not substantially destructured” or "not substantially dextrinized") or both. Therefore even if the starch is substantially destructured as applicant argues, the granules are “not substantially dextrinized", meeting the limitation of "not substantially destructured or dextrinized". Further, the instant claims or the instant specification do not define what is encompassed by the terms "substantially destructured" or "substantially dextrinized" and therefore the claims are interpreted broadly. Further the instant specification discloses that the plasticized composition forms a melt, which indicates that the granules undergo some type of disruption. Loomis et al. disclose the compositions form melts. Therefore based on the above, it does not appear that the starches of Loomis et al. are "not substantially destructured or dextrinized" because the starches of the instant claims may be pre-gelatinized and form melts. Further Applicant has not provided evidence to show that the starches of Loomis et al. are destructured. The reference discloses that destructured starches may be used as well as native and modified starches. It does not, however, disclose that destructured starches are desired as Applicant argues. In regard to the temperature, the temperature range is 20 to 225°C, however, as stated above, Applicant does not appear to provide any evidence that the conditions in Loomis et al. would cause substantial destructurization or dextrinization. In regard to Newton, Newton cures the deficiencies of Loomis et al. by disclosing the density and the dimensions suitable for delivering active ingredients. Therefore the

combination of Loomis et al. and Newton et al. meets the limitations of the instant claims.

In regard to claims 111 and 112, the starches used include native and modified starches, which would meet the limitation of the starch being not cooked or a portion of it being not cooked.

3) Claims 42, 69, 70, 84 and 108-110 were rejected under 35 U.S.C. 103(a) as being unpatentable over Loomis et al. (US 5,852,114) in view of Newton et al. (US 4,938,967) as applied to claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 69, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 in further view of Tye et al. (US 5,308,636). The rejection is maintained.

Rejection

Loomis et al. in view of Newton et al. is discussed above and discloses native and granular starches used include wheat. The combination differs from the instant claims insofar as it does not disclose the wheat used as a starch source is durum wheat.

Tye et al. disclose gellable starch based systems. The compositions are useful in a wide variety of food and industrial application (Abstract). The starches include wheat sources such as semolina flour (see Example 5).

The reference differs from the instant claims insofar as it does not disclose the starches are used in a plasticized matrix formulated into discrete particles comprising an encapsulant.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used wheat durum (semolina flour) as the wheat starch in the compositions of the combined teachings of Loomis et al. in view of Newton et al. motivated by the desire to use a wheat starch suitable for making gellable compositions that can be ingested as disclosed by Tye et al.

Response to Arguments

Applicant's Arguments

Applicant argues that the comments above regarding Loomis et al and Newton et al are applicable here and incorporated herein. Tye et al does not cure the deficiencies in the disclosures of Loomis et al and Newton et al discussed above. Even if all three references were properly combinable, applicant's claimed invention would not be obtained or rendered obvious. None of the references, taken alone or in combination teach or suggest the use of a plasticized mass comprising starch which is not substantially destructured or dextrinized. However, Loomis et al does not disclose the production of gellable compositions and it is not seen why one ordinarily skilled in the art would modify the Loomis et al composition to be gellable. Additionally, neither

Loomis et al nor Newton et al employ flour, and there is no reason to employ flour in the Loomis et al product when all that is needed is a starch. Moreover, even if the references were properly combinable, employment of semolina of Tye et al in the process and composition of Loomis et al would still result in substantial destructurization of the starch because it would be subjected to the intense extrusion conditions of Loomis et al.

Examiner's Response

See the Examiner's Response in regard to Loomis et al. in view Newton et al. and in regard to Applicant's arguments regarding the substantial destructurization of the starch due to the conditions of Loomis et al. Tye et al. cures the deficiencies of Loomis et al. and Newton et al. by disclosing different sources of starch. One of ordinary skill would reasonably conclude that the starches of Tye et al. would be suitable for the compositions of Loomis et al. in view Newton et al. because they are used in ingestible compositions. Further, one of ordinary skill in the art would recognize that if a component, such as flour, is a source of starch that it would be suitable to use it when a starch component is desired.

4) Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 62, 64-67, 69, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 were rejected under 35 U.S.C. 103(a)

as being unpatentable over Newton et al. (US 4,938,967) in view of Fishman et al. (US 5,451,673). The rejection is maintained and withdrawn in regard to claim 61.

Rejection

Newton et al. disclose pharmaceutical compositions. The dosages are preferably capsules that contain one or more units. Selection of the binder determines the rate of release of the active ingredient (col. 1, lines 19-21). The dosage may be a plurality of pellets having a dimension below about 2 mm, encompassing claims 28, 35, 37, 40, 52, 55, 56, 62, 64, 67 and 73. The pellets have a shape that is spherical (col. 7, lines 48-57). The active ingredient comprises 0.0001 to 45% of the compositions (col. 10, lines 30-35). Various active agents may be used such as tonics (encompassing claim 93), anti-inflammatory, enzymes (instant claims 46, 75, 82 and 85) and anti-viral agents (col. 13 to col. 14, line 48). The pellets may comprise a matrix binder and a coating. These serve to control the release of the active. Binders serve as carriers and include polymers such as starch and cellulose (col. 8, lines 53-68). Generally water is added to the compositions to aid in pelletisation (col. 11, lines 37-39), encompassing a water plasticizer. The matrix binder may comprise 50% of the particles (col. 10, lines 22-25). Each pellet may comprise a homogeneous blend of the active, the weighing material and the matrix binder components (col. 10, lines 58-60). Magnesium stearate also may be added to the compositions (Example 3), encompassing claims 31 and 59.

The reference differs from the instant claims insofar as it does not disclose the exact amounts of matrix material or encapsulant as recited in the instant claims and does not disclose the matrix is plasticized.

Fishman et al. disclose compositions comprising pectin and gelatinized starch. The films are useful as carriers such as tablets and encapsulation materials (col. 4, lines 33-36). The mixture of starch and pectin has high moduli and thus has many uses. Plasticizers are added to make the compositions less brittle (col. 4, lines 10-18). The compositions may be made by melt process by mixing the components together with sufficient water to allow the pectin and starch to melt at a temperature below their decomposition temperatures (col. 4, lines 53-57). The starch solution is prepared by mixing starch with water and heating it above the boiling point of water under pressure for a sufficient time to break down starch granules (col. 5, lines 1-4). Plasticizers are used in the compositions to make plasticized compositions. The compositions were plasticized at temperatures up to 200 degrees C (col. 8, lines 52-60).

The reference differs from the instant claims insofar as it does not disclose the size of the composition is up to 10 mm or that there is an encapsulant in the compositions.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used a heated plasticized starch matrix in the formulations of Newton et al. motivated by the

desire to use a composition that is suitable for carriers and encapsulation materials as disclosed by Fishman et al.

It would have been obvious to have coated the actives before incorporating them into the matrix of Fishman et al. motivated by the desire to add an additional control release mechanism for the active agent as suggested by the teachings of Newton et al.

Newton et al. disclose the active may comprise 0.0001 to 45% of the compositions. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore it would have been obvious to have used 1 to 85%, 5% to 50%, 3% to 50% and 5% to 20% of encapsulant (active agent) consistent with the In re Peterson decision.

In regards to the amounts recited in the instant claims such as the amount of matrix material, this is a result effective variable. The matrix material controls the release of the active and the active results in achieving the desired effect for the desired treatment. That being said, it would take no more than routine skill in the art to adjust the amount of matrix binder in the pellets to achieve the desired active release profile including the amount of active released in an aqueous or gastric juice environment as recited in claims 38 and 65. Therefore it would have been obvious to one of ordinary skill in the art to have used about 60% to about 95% of the matrix material in the compositions of the combined teachings of Newton et al. in view of Fishman et al. motivated by the desire to release incorporated active materials at the desired rate.

Fishman et al. disclose temperature ranges up to 200 degrees C similar to those disclosed by the instant specification up to 160 degrees C. Thus it is reasonable to conclude that the starches used by Fishman et al. are not “substantially dextrinized” or “substantially destructured”.

Response to Arguments

Applicant’s Arguments

Applicant argues that Newton et al already discloses use of a carrier that includes a gastric controlled release binder that will permit controlled release of the active ingredient from the controlled release unit while in the stomach, and the controlled release unit has a critical density of at least 2 g/ml. There is no reason to employ the composition of Fishman et al in the Newton et al formulation. Fishman et al teach that the "gelatinized starch solution is prepared by mixing starch with water and heating it above the boiling point of water under pressure for a sufficient time to break down starch granules." As discussed above, low shear mixing, low temperature and plasticizer amounts, and extrusion residence time, screw speeds, and screw configuration are employed to achieve plasticization without substantial destructurization or dextrinization of the starch. Even if the references were properly combinable, employment of a pectin and starch film forming composition of Fishman et al in the process and composition of Newton et al would still result in substantial destructurization of the starch because it would be subjected to Fishman et al.’s heating

above the boiling point of water under pressure for a sufficient time to break down starch granules.

Examiner's Response

The Examiner submits that the reason to employ the compositions of Fishman et al. in the Newton et al. formulation is to add an additional control release mechanism for the actives of Newton. Further generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Both Newton et al. and Fishman et al. disclose controlled release compositions for the release of active agents. Therefore it would have been obvious to combine the compositions of Newton et al. and Fishman et al. to form a third composition as supported by MPEP 2144.06. Further the compositions are processed under conditions that avoid their decompositions. Thus one of ordinary skill in the art would reasonably conclude that the compositions did not comprise a destructured or dextrinized starch. Furthermore, the instant claims recite using partially gelatinized starch in the compositions and therefore one of ordinary skill in the art would conclude that what Applicant considers “destructured” and “dextrinized” would not include gelatinized starches. Further, the claims recite "not substantially destructured or dextrinized", which indicates that the starch may be one or the other (either “not substantially destructured” or "not substantially dextrinized”) or both. Therefore even if

the starch is substantially destructured as applicant argues, the granules are “not substantially dextrinized", meeting the limitation of "not substantially destructured or dextrinized". Further, the instant claims or the instant specification do not define what is encompassed by the terms "substantially destructured" or "substantially dextrinized" and therefore the claims are interpreted broadly. Further the instant specification discloses that the plasticized composition forms a melt, which indicates that the granules undergo some type of disruption. Fishman et al. also disclose the compositions form melts. Therefore based on the above, it does not appear that the starches of Fishman et al are "not substantially destructured or dextrinized" because the starches of the instant claims may be partially gelatinized and form melts. In regard to conditions of Fishman et al. causing the starches to become destructured or dextrinized, Applicant does not appear to provide support that the conditions of Fishman et al. cause destructurization or dextrinization, and Fishman et al. does not disclose that destructurization or dextrinization occurs. Therefore the combination of Newton et al. in view of Fishman et al. meets the limitations of the instant claims.

5) Claims 25, 26, 28, 30, 31, 35, 37, 38-40, 46, 50, 52, 53, 55, 56, 58, 59, 62, 64-67, 69, 73, 75, 79, 81, 83, 91-93, 95-97, 101, 103, 105, 108 and 109 were rejected under 35 U.S.C. 103(a) as being unpatentable over Desaga (DE 19503993) in view of Loomis et al. (US 5,852,114). The rejection is maintained and further applied to claims 111 and 112.

Rejection

Desaga discloses compositions for supplying food ingredients or drug substances for improvement of glucose intolerance, insulin resistance or hyperlipidemia in obesity, etc. (page 1, paragraph 1). Actives include an omega-3 fatty acid with a content of at least 5% and an additional ingredient such as medium chain triglycerides with a content of at least 5% (page 1, paragraph 6). The fatty acid includes fish oil (page 1, paragraph 18) (instant claims 30, 31 and 93). The fatty acid is dispersed in a plasticized starch matrix (page 1, paragraph 7) (instant claims 30, 31, 58 and 59). Starch products include cyclodextrins, native or modified starches. Various additives include vitamins, antioxidants and pharmacologically active substances. The compositions may be formulated into pellets with a diameter of 0.1 to 3 mm (page 2, paragraph 7) (instant claims 28, 35, 37, 40, 55, 62, 67 and 73).

The reference differs from the instant claims insofar as does not disclose the amount of matrix material in the compositions or that the starch is not substantially destructured or dextrinized.

Loomis et al. disclose biodegradable thermoplastic polymer blends comprising a first polymer and a second polymer. The polymers form a homogeneous blend (Abstract). The first polymer includes hydrophobic polymers and may comprise 20% to 80% by weight of the total compositions. Polymers also include polyvinyl pyrrolidone meeting instant claims 50 and 79. The second polymer ranges from about 10% to 70% by weight of the total composition and includes polyvinyl acetate copolymers, pectins, polysaccharides, starch cellulose and alginates. A starch component is also

incorporated into the composition to impart further desirably physical properties and characteristics (col. 4, lines 63-67). The starch component includes native or granular starch, chemically modified starch, gelatinized starch and destructurized starch and combinations thereof, meeting the limitations of instant claims 108 and 109. Native and granular starch is selected from potatoes, rice, tapioca, corn, rye, oats, wheat and combination thereof (col. 8, lines 36-52). The starch component may comprise 5% to about 50%. Optional components, which may also be added to the compositions of the present invention to impart further desirable physical properties and characteristics, may be selected from the group consisting of extenders; fillers; lubricants; mold-release agents; ultraviolet stabilizers; coloring agents; anti-oxidants (instant claims 46 and 75) and combinations thereof. Lubricants include stearates and lecithin (instant 30 and 31). Stabilizers include antimicrobial agents. Extenders include soybean proteins and gelatin, meeting the limitation of instant claims 52, 83, 69, 108 and 109. The compositions may be used for the controlled delivery of pharmaceuticals or agricultural chemicals. The compositions are formulated into granule, pellets or powders, meeting instant claims 28 and 55. The reference discloses water is removed and therefore water is present meeting the limitation of the plasticizer comprising water.

The reference differs from the instant claims insofar as it does not disclose the dimensions of the granules, pellets or powders; or the amount of optional components that may be added to the compositions.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP

2144.07. It would have been obvious to one of ordinary skill in the art to have made the pellets of Desaga with the plasticized matrices comprising starch of Loomis et al. motivated by the desire to use a plasticized starch matrix suitable for delivering pharmaceuticals.

Loomis et al. disclose starch may comprise 5 to about 50% of the compositions. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore it would have been obvious to have used 40% or more of a matrix material consistent with the In re Peterson decision.

In regard to the starch not being substantially dextrinized or destructured, the starch may be a gelatinized starch which is disclosed as different from destructured starch, meeting the limitation of not substantially dextrinized or destructured.

Response to Arguments

Applicant's Arguments

Applicant argues that neither Desaga et al nor Loomis et al, taken alone or in combination teach or suggest the use of a plasticized mass comprising starch which is not substantially destructured or dextrinized. Even if the references were properly combinable, applicant's claimed products would not be obtained or rendered obvious. However, as discussed above, Loomis et al employs conditions that would result in

destructuring of starch. As discussed above, and as discussed in the present specification, low shear mixing, low temperature and plasticizer amounts, and extrusion residence time, screw speeds, and screw configuration are employed to achieve plasticization without substantial destructurization or dextrinization of the starch. Loomis et al does not teach or suggest avoiding destructuring or dextrinization, or the use of low shear or high amounts of plasticizer, or extrusion residence time, screw speeds, and screw configurations to achieve plasticization without substantial destructurization or dextrinization of the starch. To the contrary, Loomis et al employs high extrusion temperatures, a high L/D, intensive mixing conditions, and low moisture contents to obtain destructured starch and a thermoplastic composition. Even if the references were properly combinable, employment of the plasticized starch of Loomis et al in the process and composition of Desaga would result in substantial destructurization of the starch because it would be subjected to the intense extrusion conditions of Loomis et al.

Examiner's Response

The Examiner submits that Loomis et al. discloses that the starch that may be used in the compositions include native or modified starch, gelatinized starch and destructurized starch. This indicates that when native, modified or gelatinized starch is used that the starch would not be "substantially destructured" or “substantially dextrinized" because the reference distinguishes destructurized starch from the native, modified and gelatinized starches. Therefore Desaga et al. in view of Loomis suggest the use of a plasticized mass comprising starch which is not substantially destructured

or dextrinized. Further, the claims recite "not substantially destructured or dextrinized", which indicates that the starch may be one or the other (either “not substantially destructured” or "not substantially dextrinized") or both. Therefore even if the starch is substantially destructured as applicant argues, the granules are “not substantially dextrinized", meeting the limitation of "not substantially destructured or dextrinized". Further, the instant claims or the instant specification do not define what is encompassed by the terms "substantially destructured" or "substantially dextrinized" and therefore the claims are interpreted broadly. In regard to the conditions used by Loomis et al., it is asserted that Applicant does not appear to support that the conditions of Loomis et al. would actually cause the starch used in Loomis to become destructured or dextrinized. Further, although Loomis et al. does not explicitly teach or suggest avoiding destructuring or dextrinization, or the conditions disclosed by the instant specification, one of ordinary skill in the art would reasonably conclude that starch is not destructured because, as stated above, Loomis et al. disclose that native, modified, gelatinized or destructured starch may be used. Therefore Loomis et al. contemplates the resultant matrix would not comprise a destructurized starch. Also see Examiner's Response above in regard to Loomis et al. Therefore the combination of references meets the limitations of the instant claims.

In regard to claims 111 and 112, the starches used include native and modified starches, which would meet the limitation of the starch being not cooked or a portion of it being not cooked.

Obvious-Type Double Patenting (Reinstated Rejection)

Claims 25 and 52 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 15 of U.S. Patent No. 7,201,923 (previously 09/233,443, claim 21). The rejection has been reinstated. The rejection is also applied to claims 30, 31, 37-40, 42, 46, 55, 56, 58, 59, 64, 69, 70, 73, 75, 81-85, 91, 92, 95, 101, 103, 105 and 108-110.

Applicant has filed a Terminal Disclaimer on June 18, 2003. The Terminal Disclaimer was disapproved on April 12, 2012 and therefore the rejection has been reinstated.

In regard to the additionally added claims, the instant claims comprise the same components as the patented claims (patented claims 1-22). The claims differ insofar as the instant claims are genus claims insofar as the instant claims do not disclose a specific source of starch in the independent claims. The starch is further defined in the instant dependent claims. Therefore the instant claims are obvious over the patented claims

Claims 25-31, 34, 35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105 and 108-112 are rejected.

Claim 94 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Primary Examiner, Art Unit 1612